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## COMPOSITIONS AND METHODS TO LOWER GLYCOHEMOGLOBIN LEVELS

### CROSS-REFERENCE TO RELATED APPLICATIONS

The present application claims the benefit of U.S. Provisional Application Ser. No. 60/604,271, filed Aug. 25, 2004, which is hereby incorporated herein in its entirety by reference.

### TECHNICAL FIELD

This invention relates to glycohemoglobin levels, and more particularly to a compositions and methods to lower glycohemoglobin levels.

### BACKGROUND

The glucose absorbed following the ingestion of glucose-containing foods is largely responsible for a rise in the circulating glucose concentration. Dietary proteins, fats, and absorbed fructose and galactose resulting from the digestion of sucrose and lactose, respectively, have little effect on blood glucose concentration. Even short-term starvation (hours) results in a dramatic decrease in the blood glucose concentration in people with type 2 diabetes, which appears to be due largely to a rapid, progressive decrease in the rate of glycolysis.

### SUMMARY

The invention provides for diets that significantly reduce the glycohemoglobin levels in individuals with type 2 diabetes. The diets can be provided to an individual in the form of cards and/or pages with an appropriate meal plan, food items and/or pre-packaged meals, or in an electronic medium for the individuals to use to develop appropriate meal plans. For example, one diet comprises food items having a nutritional composition that consists essentially of 30% protein, 50% fats, and 20% carbohydrates, while another diet comprises food items having a nutritional composition that consists essentially of 30% protein, 40% fats, and 30% carbohydrates.

In one aspect, the invention provides an article of manufacture that includes food items for a single meal or snack, for a single day, or for multiple days. In one embodiment of the invention, the food items have a nutritional composition that consists essentially of 30% protein, 50% fats, and 20% carbohydrates. Usually, the fats consist essentially of 10% saturated fats and 40% mono- and poly-unsaturated fats. In another embodiment, the food items have a nutritional composition that consists essentially of 30% protein, 40% fats, and 30% carbohydrates.

Generally, the food items can be breakfast food items, lunch food items, dinner food items, and/or snack food items. In some embodiments, the food items can be in a pre-packaged meal. Typically, the caloric value of the sum of the food items essentially equals the daily-recommended caloric intake for an individual. According to the invention, ingestion of such food items, for a period of about 3 weeks, by an individual having elevated glycohemoglobin levels, decreases glycohemoglobin levels in the individual. Such a decrease can be statistically significant.

In another aspect, the invention provides an article of manufacture that includes food items for multiple days. In one embodiment of the invention, a portion of the food items have a nutritional composition that consists essentially of

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30% protein, 50% fats, and 20% carbohydrates and another portion of the food items have a nutritional composition that consists essentially of 30% protein, 40% fats, and 30% carbohydrates. This combination of diets can be further combined with food items that have a nutritional composition that consists essentially of 30% protein, 30% fats, and 40% carbohydrates. Alternatively, a portion of the food items have a nutritional composition that consists essentially of 30% protein, 30% fats, and 40% carbohydrates while a portion of the food items have a nutritional composition that consists essentially of 30% protein, 50% fats, and 20% carbohydrates. As another alternative, a portion of the food items have a nutritional composition that consists essentially of 30% protein, 30% fats, and 40% carbohydrates while a portion of the food items have a nutritional composition that consists essentially of 30% protein, 40% fats, and 30% carbohydrates.

In another aspect, the invention provides methods of reducing the level of glycohemoglobin in an individual. Such a method can include providing an article of manufacture that includes food items for a single day that have a nutritional composition that consists essentially of 30% protein, 50% fats, and 20% carbohydrates, and instructing the individual to consume the food items. Such instructions can be provided online or as written instructions accompanying the article of manufacture. Included in such a method, or as a separate method of reducing the level of glycohemoglobin in an individual, an article of manufacture can be provided that includes food items for a single day that have a nutritional composition that consists essentially of 30% protein, 40% fats, and 30% carbohydrates along with the appropriate instructions.

In yet another aspect, the invention provides methods of developing a meal plan for an individual having type 2 diabetes. Such a method includes providing the daily-recommended caloric intake for an individual; and selecting food items for the individual based on the individual's daily-recommended caloric intake. In an embodiment of the invention, the food items have a nutritional composition that consists essentially of 30% protein, 50% fats, and 20% carbohydrates. In another embodiment of the invention, the food items have a nutritional composition that consists essentially of 30% protein, 40% fats, and 30% carbohydrates.

Using these steps, a meal plan can be developed for the individual. The embodiments described herein can be used in combination. For example, one, two, or three weeks of food items that have a nutritional composition that consists essentially of 30% protein, 50% fats, and 20% carbohydrates, followed by one, two, or three weeks of food items that have a nutritional composition that consists essentially of 30% protein, 40% fats, and 30% carbohydrates.

According to the invention, ingestion of the food items does not result in ketosis in the individual, and results in maintenance of the individual's weight (i.e., does not result in the individual losing weight).

In still another aspect, the invention provides methods of developing a meal plan for an individual having type 2 diabetes. Such a method includes providing the daily-recommended caloric intake for an individual; and selecting food items for the individual based on the individual's daily-recommended caloric intake. In one embodiment of the invention, a portion of the food items have a nutritional composition that consists essentially of 30% protein, 50% fats, and 20% carbohydrates, and a portion of the food items have a nutritional composition that consists essentially of 30% protein, 40% fats, and 30% carbohydrates and/or 30% protein, 30% fats, and 40% carbohydrates. In another embodiment of the invention, a portion of the food items have a nutritional